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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/824,709

04/14/2004

Stephen Eliot Zweig

6809

27052

7590

11/08/2005

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EXAMINER

LA, ANH V

ART UNIT

PAPER NUMBER

2636

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/824,709

Applicant(s)

ZWEIG, STEPHEN ELIOT

Examiner

Anh V. La

Art Unit

2636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/14/04</u> .   | 6) <input type="checkbox"/> Other: ____.                                    |

### DETAILED ACTION

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.
2. The drawings are objected to because in figures 2 and 7, blank boxes need to be labeled. For example, box 1 should be labeled as - -microprocessor--.
3. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "said computing means" in line 9. There is insufficient antecedent basis for this limitation in the claim. The phrase "said computing means" should be changed to - -said computational means--.

Claim 11 recites the limitation "said computing means" in line 12. There is insufficient antecedent basis for this limitation in the claim. The phrase "said computing means" should be changed to - -said computational means--.

Claim 18 recites the limitation "said computing means" in line 13. There is insufficient antecedent basis for this limitation in the claim. The phrase "said computing means" should be changed to - -said computational means--.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-18 and 20, as far as definite, are rejected under 35 U.S.C. 102(b) as being anticipated by Soga.

Regarding claim 1, Soga discloses a unitized electronic time-temperature indicator device for rapidly assessing the acceptability of a material's thermal history, the device comprising computational means 14 and temperature measurement means 15a, wherein the device periodically samples the temperature and computes a function of temperature that is continually operative throughout a relevant temperature monitoring range of the device, wherein said function of temperature estimates an impact of time based on a detectable property of the material, and wherein the computational means generates a running sum of said function of temperature over time, the running sum is compared to a reference value, and the result of the comparison is used to generate an output signal 84, 95 to indicate the fitness for use of the material (see abstract, column 12, lines 15-65, col. 13, line 14- col. 14, line 55, col. 15, lines 1-25).

Regarding claim 2, Soga discloses a multi-element lookup table (see fig. 4).

Regarding claim 3, Soga discloses a visual output signal 84.

Regarding claim 4, Soga discloses means to enable the function of temperature

and the reference value to be automatically programmed into an assembled device (see abstract, col. 12, lines 15-65, col. 13, line 14- col. 14, line 55, col. 15, lines 1-25).

Regarding claim 5, Soga discloses a microprocessor 14 and power means being an AC power (see figure 2).

Regarding claim 6, Soga discloses all the claimed subject matter as set forth above in claim 1, but does not clearly disclose the function of temperature having a temperature resolution granularity of 10 degrees of C or smaller and a periodicity of sampling having a time resolution granularity of 2 hours or smaller. However, it would have been obvious to have the function of temperature having a temperature resolution granularity of 10 degrees of C or smaller and a periodicity of sampling having a time resolution granularity of 2 hours or smaller since it is not inventive to discover the optimum or workable ranges by routine experimentation.

Regarding claim 7, Soga discloses a lookup table that has a separate table entry (fig. 4), but does not clearly disclose the table entry spanning a temperature range of 2 degrees of C or less. However, it would have been obvious to have the table entry spanning a temperature range of 2 degrees of C or less since it is not inventive to discover the optimum or workable ranges by routine experimentation.

Regarding claim 8, Soga discloses display means conveying information pertaining to a fractional remaining stability lifetime of material that has not yet expired (abstract, col. 12, lines 15-65, col. 13, line 14- col. 14, line 55, col. 15, lines 1-25).

Regarding claim 9, Soga discloses a temperature logger (fig. 4, 10).

Regarding claim 10, Soga discloses a material dispensing device in which the

time temperature device signals if the material should be dispensed or not depending upon the acceptability of the material's thermal history (abstract, col. 12, lines 15-65, col. 13, line 14- col. 14, line 55, col. 15, lines 1-25).

Regarding claim 11, Soga discloses a unitized electronic time-temperature indicator device for rapidly assessing the acceptability of a material's thermal history, the device comprising computational means 14 and temperature measurement means 15a, wherein the device periodically samples the temperature and computes a function of temperature that is continually operative throughout a relevant temperature monitoring range of the device, and wherein said function of temperature is in the form of a multi-element lookup table (see figure 4, 10), and wherein said function of temperature approximates the impact that the relevant temperature, for that period's length of time, has on a detectable property of the material, and wherein the computational means generates a running sum of said function of temperature over time, and wherein the granularity of the function of temperature is small enough, and the frequency of time measurements is often enough, as to substantially approximate the impact of time and temperature of the detectable property of the material, and in which the running sum is compared to a reference value, and the result of the comparison is used to generate an visual output signal 84, 95 to indicate the fitness for use of the material (see abstract, column 12, lines 15-65, col. 13, line 14- col. 14, line 55, col. 15, lines 1-25), and the device contains means to allow the function of temperature and reference value to be automatically programmed into an assembled device (see abstract, col. 12, lines 15-65, col. 13, line 14- col. 14, line 55, col. 15, lines

1-25).

Regarding claim 12, Soga discloses the function of temperature and the reference value to be programmed into an assembled device by a replaceable memory chip or electronic data transfer (see figures 1a-2, 7, and 8).

Regarding claim 13, Soga discloses a temperature logger (fig. 4, 10).

Regarding claim 14, Soga discloses a microprocessor 14 and power means being an AC power (see figure 2).

Regarding claim 15, Soga discloses all the claimed subject matter as set forth above in claim 11, but does not clearly disclose the function of temperature having a temperature resolution granularity of 10 degrees of C or smaller and a periodicity of sampling having a time resolution granularity of 2 hours or smaller. However, it would have been obvious to have the function of temperature having a temperature resolution granularity of 10 degrees of C or smaller and a periodicity of sampling having a time resolution granularity of 2 hours or smaller since it is not inventive to discover the optimum or workable ranges by routine experimentation.

Regarding claim 16, Soga discloses display means conveying information pertaining to a fractional remaining stability lifetime of material that has not yet expired (abstract, col. 12, lines 15-65, col. 13, line 14- col. 14, line 55, col. 15, lines 1-25).

Regarding claim 17, Soga discloses a material dispensing device in which the time temperature device signals if the material should be dispensed or not depending upon the acceptability of the material's thermal history (abstract, col. 12, lines 15-65, col. 13, line 14- col. 14, line 55, col. 15, lines 1-25).

Regarding claim 18, Soga discloses a method for monitoring the storage life of materials, the method consisting of modeling the thermal degradation characteristics of the material as a function of temperature and time based upon a plurality of experimental data points, using the time-temperature parameters from this model to program a unitized electronic time-temperature indicator device to automatically assess the acceptability of material's thermal history, the device comprising computational means 14 and temperature measurement means 15a, wherein the device periodically samples the temperature and computes a function of temperature that is continually operative throughout a relevant temperature monitoring range of the device, and wherein said function of temperature approximates the impact that the relevant temperature, for that period's length of time, has on a detectable property of the material, and wherein the computational means generates a running sum of said function of temperature over time, and wherein the granularity of the function of temperature is small enough, and the frequency of time measurements is often enough, as to substantially approximate the impact of time and temperature of the detectable property of the material, and in which the running sum is compared to a reference value, and the result of the comparison is used to generate an visual output signal 84, 95 to indicate the fitness for use of the material (see abstract, column 12, lines 15-65, col. 13, line 14- col. 14, line 55, col. 15, lines 1-25).

Regarding claim 20, Soga clearly discloses the device remaining associated with the material throughout the majority of the material's storage life (see abstract, column 12, lines 15-65, col. 13, line 14- col. 14, line 55, col. 15, lines 1-25).



6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soga in view of Nicholson.

Regarding claim 19, Soga discloses all the claimed subject matter as set forth above in claim 18, but does not clearly disclose the materials being selected from the group consisting of food, chemicals, biotherapeutics, drugs, medical diagnostics, blood, and blood products. Nicholson teaches the use of monitoring materials being selected from the group consisting of food, chemicals, biotherapeutics, drugs, medical diagnostics, blood, and blood products (abstract, column 1, lines 5-35, col. 2, lines 35-65, fig. 1, 3, 4). It would have been obvious at the time the invention was made to a person having ordinary skill in the art to include the materials being selected from the group consisting of food, chemicals, biotherapeutics, drugs, medical diagnostics, blood, and blood products to the method of Soga as taught by Nicholson for the purpose of protecting the materials.

Regarding claim 21, Soga discloses a multi-element lookup table (see fig. 4).

### **Double Patenting**

8. Claims 1, 3-6, 8, and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 5, 6, and 8, respectively, of U.S. Patent No. 6,950,028 (U.S. Application Number 10/634,297). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 3, 4, 5, 6, and 8 of U.S. Patent No. 6,950,028 (U.S. Application Number 10/634,297) contains all the limitations cited in claims 1, 3-6, 8, and 10 of the present invention.

9. Claims 2, 7, 9, 11-18, and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, and 9-15, respectively, of U.S. Patent No. 6,950,028 (U.S. Application Number 10/634,297). The claims in the U.S. Patent No. 6,950,028 (U.S. Application Number 10/634,297) recite all the claimed subject matter as claimed in claims 2, 7, 9, 11-18, and 20 of the present invention, but still do not disclose the use of a multi-element lookup table, a temperature logger, means to allow the function of temperature and reference value to be automatically programmed into an assembled device, the device remaining associated with the material throughout the majority of the material's storage life. Soga discloses the use of a multi-element lookup table (see figure 4), a temperature logger (figures 4, 10), means to allow the function of temperature and reference value to be automatically programmed into an assembled device (see abstract, col. 12, lines 15-65, col. 13, line 14- col. 14, line 55, col. 15, lines 1-25), the device remaining associated

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with the material throughout the majority of the material's storage life (see abstract, column 12, lines 15-65, col. 13, line 14- col. 14, line 55, col. 15, lines 1-25). It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the claimed invention of the U.S. Patent No. 6,950,028 (U.S. Application Number 10/634,297) to include a multi-element lookup table, a temperature logger, means to allow the function of temperature and reference value to be automatically programmed into an assembled device, the device remaining associated with the material throughout the majority of the material's storage life for the purpose of monitoring the thermal history of material.

10. Claims 19 and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 of U.S. Patent No. 6,950,028 (U.S. Application Number 10/634,297) in view of Soga and Nicholson. The claims in the U.S. Patent No. 6,950,028 (U.S. Application Number 10/634,297) as modified by Soga recite all the claimed subject matter as claimed in claims 19 and 21 of the present invention, but still do not disclose clearly disclose the materials being selected from the group consisting of food, chemicals, biotherapeutics, drugs, medical diagnostics, blood, and blood products. Nicholson teaches the use of monitoring materials being selected from the group consisting of food, chemicals, biotherapeutics, drugs, medical diagnostics, blood, and blood products (abstract, column 1, lines 5-35, col. 2, lines 35-65, fig. 1, 3, 4). It would have been obvious at the time the invention was made to a person having ordinary skill in the art to include the materials being selected

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from the group consisting of food, chemicals, biotherapeutics, drugs, medical diagnostics, blood, and blood products to modify the claimed invention of the U.S.

Patent No. 6,950,028 (U.S. Application Number 10/634,297) (as modified by Soga) as taught by Nicholson for the purpose of protecting the materials.

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Pedoeem, Vidaillac, and Singh teach thermal monitoring systems.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anh V. La whose telephone number is (571) 272-2970. The examiner can normally be reached on Mon-Fri from 9:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Hofsass can be reached on (571) 272-2981. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**ANH V. LA**  
**PRIMARY EXAMINER**

Anh V La  
Primary Examiner  
Art Unit 2636

AI  
September 17, 2005